## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 50-757 / S-003

**CHEMISTRY REVIEW(S)** 

003	02/24/99
Y NAMI Ilin, and	clarithromycin
HER DA	
	LATED DA/DMF(s) DA 20-406
lansopraz 0 mg BIA ets), and 5 in capsulo	500 mg
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HO	OH3 3H2O
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tly appro- ubmitted : w division n fact, tha	n had
tion of th	ie

SUPPLEMENTAL NDA	1. ORGANIZA	· · · · · · · · · · · · · · · · · · ·					
CHEMIST'S REVIEW # 1	HFD-590	·	50-757				
3. NAME AND ADDRESS OF APPLICANT (City and State)			4. AF NUMBER				
TAP Holdings Inc. Attention: Linda J. Peters			OCUMENT(S) MBERS DATES				
2355 Waukegan Road		1	P-003 02/24/99				
Deerfield, IL 60015		30	r-003 02/24/99				
6. NAME OF DRUG	DDIETA	DV NAME					
PREVPAC®	PRIETARY NAME le, amoxicillin, and clarithromycin						
8. SUPPLEMENT(S) PROVIDES FOR:	9. AMENDMENTS AND						
A packaging change in which the <u>currently approved</u> blister material			OTHER DATES				
will be replaced with		1	/A				
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPE		12. RELATED				
anti-ulcer	X  <del>   </del>	TC	IND/NDA/DMF(s)				
			NDA 20-406				
13. DOSAGE FORM(S)	14. POTENO						
Tablets and Capsules		REVACID (lansoprazole delayed-					
			500 mg BIAXIN				
	,	mycin tablets), and 500 mg					
16 CHEMICAL NAME	TRIMOX						
15. CHEMICAL NAME			MEMORANDA N/A				
О ночаньой и	_ QCH₃	<u> </u>	0				
		но.	HO√				
N OH <sub>3</sub> H <sub>3</sub> C O H	CH3 H	N 0H3 3H <sub>2</sub> O					
	CH <sub>3</sub> OH <sub>3</sub>	Нъ	N CH3				
<b>√</b> `00H20F3 0H20H3 0	CH <sub>2</sub> CH <sub>3</sub> O H O N(CH <sub>3</sub> )2						
<b>04</b> - <b>1</b> √0		(2S,5R,6R)-6- $[(R)$ -(-)-2-amino-2- (p-hydroxyphenyl) acetamido]-					
2-[[[3-methyl-4-(2,2,2-tri-							
fluoroethoxy)-2-pyridyl]-	73	3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-					
methyl]sulfinyl] benzimidazole 6-O-methyleryth		carboxylic acid trihydrate					
$C_{16}H_{14}F_3N_3O_2S$ $C_{38}H_{69}NO_{13}$	•	C <sub>16</sub> H <sub>18</sub> N <sub>3</sub> O <sub>5</sub> S • 3 H <sub>2</sub> O					
17. COMMENTS							
This supplemental application provides for a packaging change in which the currently approved blister							
material will be replaced with			submitted as a				
changes-being-effected supplement and was accepted as such because another review division had							
apparently already accepted a similar CBE supplement for a related drug product (in fact, that CBE							
supplement was already approved).							
In support, the applicant provided a description of the change, including an explanation of the							
difference between the old and new blister materials, data indicating that the protective properties							
(moisture barrier) were better in the new blister materials, and a copy of the approval letter for NDA							
20-406/S-025.							
No deficiencies were noted.							
18. CONCLUSIONS AND RECOMMENDATIONS							
Recommend: APPROVAL.							
19. REVIEWER	NUDE	I	DATE COLER ETER				
NAME SIGNAT	UKE		DATE COMPLETED				
John Smith 08/19/99  20. CONCURRENCE: HFD-590/NSchmuff							
	ISmith	Τv	MO/PHonkins				
DISTRIBUTION   X   Original Jacket   X	JSmith	X	MO/RHopkins				

## CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER: 50-757 / S-004** 

**CHEMISTRY REVIEW(S)** 

SUPPLEMENTAL NDA		1. ORGANIZ	ATION	2. NDA NUMBER			
CHEMIST'S REVIEW # 1		HFD-59		50-757			
				4. AF NUMBER			
TAP Holdings Inc.				5. DOCUMENT(S)			
Attention: Janet L. Haskins			1	MBERS DATES			
2355 Waukegan Road			1	SCP-004 06/23/99			
Deerfield, IL 60015							
6. NAME OF DRUG		7. NONPR	OPRIETA	RY NAME			
PREVPAC®		lansopraz	ole, amox	icillin, and clarithromycin			
8. SUPPLEMENT(S) PROVIDES FOR:			9. AMENDMENTS AND				
Formulation and packaging changes related to the reformulation of			OTHER DATES				
BIAXIN® (clarithromycin tablets) by i	ts manufact			/A			
10. PHARMACOLOGICAL CATEGO	RY	11. HOW DISPE	ENSED	12. RELATED			
anti-ulcer		X  <del>B</del>	OTC	IND/NDA/DMF(s)			
				NDA 50-662			
13. DOSAGE FORM(S)			ICY (CIE				
Tablets and Capsules				O (lansoprazole delayed-			
	(clarithro			500 mg BIAXIN			
				blets), and 500 mg			
44 CURRECAL MARK		I IRIMO		illin capsules)			
15. CHEMICAL NAME	15. CHEMICAL NAME			MEMORANDA N/A			
Q	н СНз н₃С Н "	C OCH3	<u></u>	N/A.			
H I	HOW HICK		но. 🔨	но√			
N OH HIC.	√ h √	CH <sub>3</sub>		N OH3 3H20			
HO		CH <sub>3</sub> CH <sub>3</sub>		N S COH3			
oat <sub>2</sub> ar <sub>3</sub>	CH2CH3 0	H O N(C)+1)2	H <sub>2</sub>	*			
	он <sub>с</sub>	_0	(2S, 5R, 6)	R)-6-[(R)-(-)-2-amino-2-			
	(6	H <sub>3</sub> OH	(p-hydro	xyphenyl) acetamido]-			
2-[[[3-methyl-4-(2,2,2-tri-				3,3-dimethyl-7-oxo-4-thia-1-			
fluoroethoxy)-2-pyridyl]-				azabicyclo[3.2.0]heptane-2-			
· · · · · · · · · · · · · · · · · · ·				carboxylic acid trihydrate			
	L <sub>69</sub> NO <sub>13</sub>		$C_{16}H_{18}N_{2}$	,O <sub>5</sub> S • 3 H <sub>2</sub> O			
17. COMMENTS			•	1 . 11			
This supplemental application provide							
reformulation of BIAXIN® (clarithron submitted formulation changes to NDA							
problems associated with the 250-mg tablets, there were no such problems with the 500-mg tablets, and SCF-025 was eventually approved (for the 500-mg tablets only) on 10/22/99.							
TAP's packaging changes associated with the smaller, reformulated BIAXIN 500-mg tablets mainly							
concern a decrease in the size of the bl	ister cavity	and the changes	J'1 1	- CCD 002 - 311			
required to accomplish this. The blister materials and foil backing described in SCP-003 will be							
used. The first batch of product made with reformulated 500-mg BIAXIN tablets and resized packaging							
will be placed into the long term stability program. No deficiencies were noted.							
18. CONCLUSIONS AND RECOMMENDATIONS Recommend: APPROVAL.							
19. REVIEWER							
NAME				DATE COMPLETED			
John Smith			10/22/99				
20. CONCURRENCE: HFD-590/NSchm	uuff			I UI EEI / /			
DISTRIBUTION X Original Jacket	X	JSmith	X	MO/RHopkins			
X Division File	$\frac{\lambda}{x}$	NSchmuff	$\frac{\lambda}{X}$	CSO/JFritsch			
A Division rile		Nocillium		C5O/JI HISCH			